UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,066	01/24/2005	Stanley George Bonney	PG4884USw	7458

23347 7590 04/03/2009

GLAXOSMITHKLINE
CORPORATE INTELLECTUAL PROPERTY, MAI B482
FIVE MOORE DR., PO BOX 13398
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER	
PATEL, NIHIR B	

ART UNIT	PAPER NUMBER
3772	

NOTIFICATION DATE	DELIVERY MODE
04/03/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM
LAURA.M.MCCULLEN@GSK.COM
JULIE.D.MCFALLS@GSK.COM

Office Action Summary	Application No.	Applicant(s)	
	10/523,066	BONNEY ET AL.	
	Examiner	Art Unit	
	NIHIR PATEL	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. In view of the Appeal Brief filed on December 8th, 2008, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercixe one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Patricia Bianco/
Supervisory Patent Examiner Art Unit 3772

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims **1, 2, 13, 15, 17-20, 22 and 23** are rejected under 35 U.S.C. 102(b) as being anticipated by Makiej, Jr. (US 5,002,048).

4. **As to claim 1,** Makiej teaches an apparatus that comprises a first medicament dispenser **18** containing the first medicament **(see fig. 1; col. 2 lines 5-15)**; at least one further medicament dispenser **20** containing the at least one further medicament **(see fig. 1; col. 2 lines 5-15)**; and a mixing chamber comprising inlets for receiving medicament from each medicament dispenser and an outlet for delivery of the combination medicament product **(see fig. 1; the mouthpiece area is defined as the mixing chamber)**, wherein the first medicament dispenser and the at least one further medicament dispenser enable the first and the at least one further medicament to be kept separate until the point of delivery **(see fig. 1; col. 2 lines 30-40)**, and he first medicament dispenser is different in type to the at least one further medicament dispenser **(see col. 2 lines 25-31)**.

5. **As to claim 2,** Makiej teaches an apparatus wherein the device comprises the first medicament dispenser and only one further medicament dispenser **(see fig. 1)**.

6. **As to claim 13,** Makiej teaches an apparatus that comprises a coupled actuator for the first medicament dispenser and the at least one further medicament dispenser **(see fig. 1)**.

7. **As to claim 15,** Makiej teaches an apparatus wherein the outlet communicates with a common mouthpiece **(see fig. 1)**.

8. **As to claim 17,** Makiej teaches an apparatus wherein the first medicament dispenser includes a medicament container for containing the first medicament and the at least one further medicament dispenser includes at least one further medicament container for containing the at least one further medicament **(see fig. 1; col. 2 lines 5-15)**.

9. **As to claim 18,** Makiej teaches an apparatus wherein the first medicament container contains the first medicament and the at least one further medicament container contains at least one further medicament **(see fig. 1; col. 2 lines 25-31)**.

10. **As to claim 19,** Makiej teaches an apparatus wherein the first medicament comprises a bronchodilator **(see col. 2 lines 55-65)** and at least one further medicament comprises an anti-inflammatory **(see col. 3 lines 1-10)**.

11. **As to claim 20,** Makiej teaches an apparatus wherein the bronchodilator is a beta-agonist and the anti-inflammatory is a steroid **(see col. 3 lines 1-15)**.

12. **As to claim 22,** Makiej teaches an apparatus wherein the anti-inflammatory is selected from the group consisting of a beclomethasone ester, fluticasone ester, budesonide and any salt or solvates thereof and mixtures thereof **(see col. 3 lines 1-10)**.

13. **As to claim 23,** Makiej teaches method steps of providing a patient in need thereof a medicament dispenser and dispensing a combination medicament product from the device **(see fig. 1)**.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims **3-8, 11 and 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Makiej, Jr. (US 5,002,048).

17. **As to claims 3-8, 11 and 12**Makiej substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose the first medicament dispenser that is selected from the group consisting of a reservoir dry powder inhaler (RDPI), a multi dose dry powder inhaler (MDPI), a unit dose dry powder inhaler (UDPI), a metered dose inhaler (MDI) and a liquid spray inhaler (LSI) and the at least one further medicament dispenser is selected from the group consisting of a reservoir dry powder inhaler (RDPI), a multi dose dry powder inhaler (MDPI), a unit dose dry powder inhaler (UDPI), a metered dose inhaler (MDI) and a liquid spray inhaler (LSI). It would have been obvious matter of design choice to provide a first medicament dispenser that is selected from the group consisting of a reservoir dry powder inhaler (RDPI), a multi dose dry powder inhaler (MDPI), a unit dose dry powder inhaler (UDPI), a metered dose inhaler (MDI) and a liquid spray inhaler (LSI) and the at least one further medicament dispenser is selected from the group consisting of a reservoir dry powder inhaler (RDPI), a multi dose dry powder inhaler (MDPI), a unit dose dry powder inhaler (UDPI), a metered dose inhaler (MDI) and a liquid spray inhaler (LSI) in order to provide the patient with the proper treatment, since

applicant has not disclosed that providing a first medicament dispenser that is selected from any of the above solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with all types of combination as described in the Makiej's reference, as long as the patient gets the correct treatment.

17. Claims **9, 10 and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Makiej, Jr. (US 5,002,048) in view of Casper et al. (US 2007/0017513).

18. **As to claim 9,** Makiej substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a multi dose blister pack that comprises plural blisters arranged sequentially along an elongate strip. Casper discloses an apparatus that does provide a multi dose blister pack that comprises plural blisters arranged sequentially along an elongate strip **(see paragraphs [0082] and [0083]).** Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Makiej's invention by providing a multi dose blister pack that comprises plural blisters arranged sequentially along an elongate strip as taught by Casper in order to provide the patient with the proper treatment.

19. **As to claim 10,** Makiej substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose the strip form multi-dose blister pack that comprises an elongate base sheet having plural blisters pockets defined therein; and secured thereto and elongate lid sheet, wherein the elongate base sheet and the lid sheet are peelably separable to enable access to the blister pockets. Casper discloses an apparatus that does provide the strip form multi-dose blister pack that comprises an elongate base sheet having plural blisters pockets defined therein; and secured thereto and elongate lid sheet, wherein the elongate base sheet and the lid sheet are peelably separable to enable access to the blister pockets **(see figs. 3A, 3B, 4A**

and 4B; paragraphs [0082] and [0083]). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Makiej's invention by providing a strip form multi-dose blister pack that comprises an elongate base sheet having plural blisters pockets defined therein; and secured thereto and elongate lid sheet, wherein the elongate base sheet and the lid sheet are peelably separable to enable access to the blister pockets as taught by Casper in order to provide the patient with the proper treatment.

20. **As to claim 16,** Makiej substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose a breath sensor for sensing the breath of a patient wherein actuation of the first medicament dispenser and/or the at least one further medicament dispenser is responsive to the breath sensor. Casper discloses an apparatus that does provide a breath sensor for sensing the breath of a patient wherein actuation of the first medicament dispenser and/or the at least one further medicament dispenser is responsive to the breath sensor (**see paragraph [0018]**). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Makiej's invention by providing a breath sensor for sensing the breath of a patient wherein actuation of the first medicament dispenser and/or the at least one further medicament dispenser is responsive to the breath sensor as taught by Casper for providing control of medicament introduction into a patient's inspired air stream.

21. Claim **21** is rejected under 35 U.S.C. 103(a) as being unpatentable over Makiej, Jr. (US 5,002,048) in view of Haikarainen et al. (US 6,810,873).

22. **As to claim 21,** Makiej substantially discloses the claimed invention; see rejection of claim 1 above, but does not disclose bronchodilator that is selected from the group consisting of salbutamol, salmeterol, formoterol and any salts or solvates thereof and mixtures thereof.

Haikarainen discloses an apparatus that does provide bronchodilator that is selected from the group consisting of salbutamol, salmeterol, formoterol and any salts or solvates thereof and mixtures thereof **(see col. 3 lines 40-45)**. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Makiej's invention by providing bronchodilator that is selected from the group consisting of salbutamol, salmeterol, formoterol and any salts or solvates thereof and mixtures thereof in order to provide the patient with the correct treatment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772
03/30/09